#2456

No. 11,496

IN THE

United States Circuit Court of Appeals

For the Ninth Circuit

HARRY CAVASSA,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

Upon Appeal from the District Court of the United States for the Northern District of California, Southern Division.

BRIEF FOR APPELLEE.

FRANK J. HENNESSY,
United States Attorney,
EDGAR R. BONSALL,
Assistant United States Attorney,
Post Office Building, San Francisco 1, California
Attorneys for Appellee.

LEONARD D. HARDY,
Attorney, Federal Security Agency,
Of Counsel.

PERNAU-WALSH PRINTING CO., SAN FRANCISCO

Subject Index

Table of Authorities Cited

Statutes

Miscellaneous

No. 11,496

IN THE

United States Circuit Court of Appeals

For the Ninth Circuit

HARRY CAVASSA,

Appellant,

vs.

UNITED STATES OF AMERICA,

Appellee.

Upon Appeal from the District Court of the United States for the Northern District of California, Southern Division.

BRIEF FOR APPELLEE.

STATEMENT OF FACT.

This is an appeal from a judgment of conviction of the United States Court for the Northern District of California, Southern Division, for violation of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U.S.C. 301, et seq. In each of the six counts of the information (R. 2-20) it is alleged that certain articles of drug were shipped in interstate commerce to San Francisco, California and subsequently were sold by the original consignee to the appellant who owns and operates the Peninsula Drug Company in San Francisco; that subsquently, while the drugs were being held for sale, the appellant did certain acts which

resulted in the drugs being misbranded within the meaning of Section 352(f), Title 21, U.S.C., and that the doing of such acts with respect to the articles of drug constituted a violation of Section 331(k), Title 21, U.S.C.

It was alleged in Counts I, II, V and VI of the information that although the articles of drug bore no directions for use as required by Sec. 352(f)(1), Title 21 U.S.C., they were lawfully shipped in interstate commerce since they were exempt from the provisions of that section by certain regulations promulgated under authority granted therein, in that the drugs were labeled in part "Caution: To be Used Only By or on Prescription of a Physician." (21 CFR CUM. SUPP. Sec. 2.106(b)(3).) It was also charged in Counts I, II, V, and VI of the information that the appellant caused this exemption to expire, under the terms of the regulation which by it was created, by disposing of the articles of drug other than to physicians or under labels bearing directions for use as specified in prescriptions of physicians; that having caused the exemption to Sec. 352(f)(1), Title 21 U.S.C. to expire, the articles of drug were thereby misbranded, within the meaning of said section, inasmuch as their labeling failed to bear adequate directions for use.

In Count III, the appellant was charged with misbranding an article of drug, within the meaning of Section 352(f)(1) and (2), in that he caused said drug to be removed from its original container and

repacked in an envelope without a physician's prescription therefor and without a label bearing directions for use specified in a prescription of a physician, and without the label containing adequate warning against use in those pathological conditions and by children where its use may be dangerous to health, or against unsafe dosage. The envelope containing the drug bore the single word, "Seconal."

Count IV charged the same offense as Count III, it being alleged that the appellant misbranded an article of drug, seconal sodium, by removing a quantity of said drug from its immediate container and placing it in an *unlabeled* vial. No direction for use appeared on the label of the drug, as repacked, and there was no marking as to unsafe dosage, or against use in those pathological conditions or by children where its use might be dangerous to health.

The trial was before the Court without a jury. The acts of misbranding were stipulated to and no issues of fact were involved. The appellee submitted evidence tending to establish that the articles of drug in question were habit-forming and could be dangerous to health when used indiscriminately by a layman, and that it was in the interest of the people and for their protection that such drugs be used only by physicians or under their direction. The appellant testified to certain facts for the purpose of establishing that the drugs, when misbranded, were no longer in the original package in which they were shipped in interstate commerce and that they were commingled with

the general mass of property in the State of California.

At the conclusion of the trial, the Court found the defendant guilty of all six counts and fined him Two Hundred Dollars ($200.00) on each count, a total of Twelve Hundred Dollars ($1200.00.)

RELEVANT STATUTORY AND REGULATORY PROVISIONS.

The following sections of Title 21 U.S.C. and Regulations promulgated thereunder are pertinent to this case:

Sec. 331. The following acts and the causing thereof are hereby prohibited:

> (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

Sec. 333:

> (a) Any person who violates any of the provisions of Section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1000 or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or

a fine of not more than $10,000, or both such imprisonment and fine.

Sec. 352:

A drug or device shall be deemed to be misbranded—(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; *Provided* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

The pertinent part of the regulation (21 CFR CUM. SUPP. S. 2.106) promulgated under the proviso of Sec. 352 is as follows:

(b) A shipment or other delivery of a drug or device shall be exempt from compliance with the requirements of clause (1) of section 502(f) of the Act [21 U.S.C. 352(f)] if—

(3) the label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a .....", or "Caution: To be used only by a .....", the blank to be filled in by the word "Physician", "Dentist", or "Veterinarian", or any combination of two or all of such words, as the case may be;

Such exemption shall remain valid until all of such shipment or delivery is used by physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device, or is dispensed upon, and under labels bearing the directions for use specified in, prescriptions of such physicians, dentists, or veterinarians. But if such shipment or delivery, or any part thereof, is otherwise disposed of as a drug or device, such exemption shall thereupon expire. The causing by any person of such an exemption so to expire shall be considered to be an act of misbranding for which such person shall be liable unless, prior to such disposition, such drug or device is relabeled to comply with clause (1) of section 502(f) of the Act [21 U.S.C. 352(f)]. [Effective October 7, 1941 to October 10, 1945.]

ISSUES INVOLVED.

The appellant argues three propositions in support of his contention that the judgment of the District Court should be reversed (appellant's brief, page 6.)

I. The Court erred in holding retail sales made by appellant were in interstate commerce.

II. The Court erred in construing the Federal Food, Drug, and Cosmetic Act, and particularly Section 331(k) of Title 21 of the United States Code as applying to the acts of appellant, because such acts were in intrastate commerce and not in interstate commerce.

III. The Court erred in holding that the Federal Food, Drug, and Cosmetic Act and particularly Section 331(k) of Title 21 of the United States Code, so construed as applying to the intrastate acts of appellant was valid and constitutional and not in violation of the Tenth Amendment to and Article I, Section 8, Paragraph 3 of the Constitution of the United States of America.

The first two points presented by the appellant are apparently grounded on the theory that section 331(k) has reference only to acts done in connection with articles in interstate commerce. The intent and purpose of this subsection, as revealed by the language, is not limited in its application to articles in interstate commerce but extends to the doing of acts with respect to articles *after* they have been shipped in interstate commerce and while being held for sale. Section 331 (b) Title 21 U.S.C., prohibits misbranding *in* interstate commerce. It is the government's position that it is immaterial whether the articles of drug misbranded by the appellant were in interstate commerce or intrastate commerce at the time they were misbranded. If the articles had at one time been shipped in interstate commerce and were subsequently misbranded by the appellant while being held for sale, such acts of misbranding constituted a violation of Sec. 331(k) and the appellant is liable to the penalties set out in Sec. 333, Title 21, U.S.C.

An examination of the records fails to disclose that the Court, in finding the appellant guilty as charged,

held that the acts of misbranding occurred in interstate commerce. There is nothing in the records indicating whether the Court considered this a material element of the appellee's case. The pleadings disclosed that the government did not charge that the acts of the appellant were committed while the articles of drug were in interstate commerce. It was alleged that the drugs were misbranded while being held for sale after shipment in interstate commerce, and that this constituted a violation of Sec. 331(k).

Thus, since the government believes that it is immaterial whether the articles were in interstate commerce or intrastate commerce at the time of the misbranding in order to constitute a violation of Sec. 331(k), and inasmuch as the appellant contends that the drugs were in intrastate commerce when misbranded, the government is willing to concede, for the purpose of this case, that the acts of the appellant, which resulted in the misbranding of the drugs, occurred at a time when the said articles were in intrastate commerce while held for sale and that the acts of sale constituted intrastate commerce.

Thus, the sole problem for consideration is that raised by the third proposition of the appellant.

ARGUMENT.

THE COURT DID NOT ERR IN HOLDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND PARTICULARLY SECTION 331 (k), TITLE 21, U.S.C., AS APPLIED TO THE ACT OF APPELLANT, VALID AND CONSTITUTIONAL AND NOT IN VIOLATION OF ARTICLE I, SECTION 8, PARAGRAPH 3 OF, AND THE TENTH AMENDMENT TO THE CONSTITUTION OF THE UNITED STATES.

The appellant contends that his acts, which resulted in the misbranding of the articles of drug, were done in intrastate commerce and therefore are not subject to Federal control. The appellee, as previously stated, contends that this factor is immaterial in the present case and concedes, for the purpose of this case, that the articles of drug were held for sale in intrastate commerce, after shipment in interstate commerce, at the time of the commission of the prohibited acts. Thus the issue is narrowed to the often considered problem of the extent of the power granted the legislative branch of the Federal Government in Article I, Section 8, Paragraph 3 of the Constitution of the United States. If the power to regulate commerce among the several States includes the power to control intrastate activities which directly affect commerce between the States, and if the acts of the appellant so affected such commerce, then the Congress of the United States had the power to control those acts of the appellant.

I. THE CONSTITUTIONAL POWER OF CONGRESS TO REGULATE INTERSTATE COMMERCE EXTENDS TO INTRASTATE ACTS WHICH DIRECTLY AFFECT SUCH COMMERCE.

The power of Congress to regulate interstate commerce is plenary in scope, may be exercised to its utmost extent, and acknowledges no limitations other than that prescribed in the Constitution. *Gibbons v. Ogden,* 9 Wheat. 196; *Second Employer's Liability Cases,* 223 U.S. 1, 47. It is no objection to the exertion of the power that its exercise is attended by the same incidents which attend the exercise of the police power of the States. *United States v. Carolene Products Co.,* 304 U.S. 144, 147; *United States v. Rock Royal Cooperative Inc.,* 307 U.S. 533, and transportation is not the sole test for determining the scope of Congressional authority under the commerce clause. *Chicago & N. W. Ry. Co. v. Bolle,* 284 U.S. 74; *Dehnke-Walker Milling Co. v. Bondurant,* 257 U.S. 282, 291. The power granted Congress under the commerce clause of the Constitution extends to every instrumentality or agency by which interstate commerce is carried on; and the full control by Congress of the subjects committed to its regulation is not to be denied or thwarted by the commingling of interstate and intrastate operations. *The Minnesota Rate Cases,* 230 U.S. 352, 399. The power extends to those activities intrastate which so affect interstate commerce, or the exertion of the power of Congress over it, as to make regulation of those intrastate activities appropriate means to the attainment of a legitimate end, the effective exertion of the granted power to regulate interstate commerce. *United States v.*

Wrightwood Dairy Co., 315 U.S. 110, 119; *National Labor Relations Board v. Fainblatt,* 306 U.S. 601, 605-606. The power includes the ability to deal with a host of acts which are not in themselves interstate commerce but, because of their relation to and influence upon interstate commerce, come within the power of Congress. *United States v. Ferger,* 250 U.S. 199, 203; *Weiss v. United States,* 308 U.S. 321, 327. Note *Brooks v. United States,* 267 U.S. 432.

Congress may adopt not only means which are necessary, but those which are convenient, to the exercise of the commerce power, *Seven Cases v. United States,* 239 U.S. 510, 515, and may itself determine the means appropriate for this purpose. *McDermott v. Wisconsin,* 228 U.S. 115. The regulation of commerce among the several States includes the power to enact all appropriate legislation for its protection or advancement, to adopt measures to promote its growth and insure its safety and to foster, protect, control and restrain. *National Labor Relations Board v. Jones & Laughlin Steel Corp.,* 301 U.S. 1, 36-37.

Recent Supreme Court cases have sanctioned federal regulation of some phases of intrastate activities. See for example *Currin v. Wallace,* 306 U.S. 1; *Mulford v. Smith,* 307 U.S. 38; *United States v. Rock Royal Cooperative Inc.,* 307 U.S. 533; *United States v. Darby,* 312 U.S. 100; *United States v. Wrightwood Dairy Co.,* 315 U. S. 110. These cases illustrate that Congress may not only prevent the interstate transportation of a proscribed product but may also stop the initial step toward the transportation, the pro-

duction of goods with the purpose of transporting them. See *United States v. Darby,* 312 U.S. 100, at p. 117. The *Darby* case also points out that Congress may regulate intrastate transactions after transportation has ended, when such transactions are so commingled with or related to interstate commerce that all must be regulated if the interstate commerce is to be effectively controlled. To illustrate this point, the Supreme Court at p. 121, cited *McDermott v. Wisconsin,* 228 U.S. 115, saying:

> "It [Congress] may prohibit the removal at destination, of labels required by the Pure Food and Drugs Act to be affixed to articles transported in interstate commerce."

Interstate commerce may be affected by the receipt or sale of products after transportation, *National Labor Relations Board v. Abell,* 97 F. (2d) 951, 955 (C.C.A. 4). Thus, in *National Labor Relations Board v. Levour,* 115 F. (2d) 105, 109 (C.C.A. 1), cert. denied 321 U.S. 682, the Court said:

> "It has long been held that a sale involving interstate transportation is not removed from Congressional regulation because that sale itself is intrastate, either before or after the transportation."

Goods that have been transported in interstate commerce have the benefit of the protection appropriate to interstate commerce though the original packages have been broken and the contents subdivided. *Baldwin v. Seelig,* 294 U.S. 511, 526. The benefit of the protection appropriate to interstate

commerce is broad enough, we submit, to require that goods shipped interstate remain properly labeled, in accordance with federal law, while still in the channels of commerce, whether interstate or intrastate. If the power of Congress is broad enough to require that labels which comply with federal law not be *removed* from goods in intrastate commerce that have used the channels of interstate commerce (*McDermott v. Wisconsin,* 228 U.S. 115), then Congress may likewise penalize *tampering* with such labeling.

II. IN THE ENACTMENT OF SECTION 331(k), TITLE 21, U.S.C. CONGRESS INTENDED TO EXERT ITS CONSTITUTIONAL POWER TO THE FULLEST EXTENT.

That Congress, in enacting Section 331(k), intended to exercise all authority over interstate commerce granted under the Constitution is apparent from an examination of the legislative history of this section. In H. R. Report No. 2139, 75th Congress (2d) Sess. 1938), submitted by the Committee on Interstate and Foreign Commerce to accompany S. 5, which became the Federal Food, Drug, and Cosmetic Act, it was stated, with respect to Sec. 331(k):

> "In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment."

III. CONGRESSIONAL CONTROL OVER INTRASTATE ACTIVITIES THAT AFFECT INTERSTATE COMMERCE EXTENDS TO LABELING OF ARTICLES OF DRUG HELD FOR SALE AFTER SHIPMENT IN INTERSTATE COMMERCE.

Having determined that Congress may control intrastate activities which affect interstate commerce, consideration must be given to whether the misbranding of drugs after shipment in interstate commerce and while being held for sale by the retailer is an intrastate activity which so affects commerce between the several states as to subject it to Congressional control.

Under some statutes the determination as to whether an activity affects interstate commerce is left to the Courts, under some the determination is made by administrative boards or agencies, and under others Congress itself has said that an activity affects the commerce. This was pointed out and illustrated in the *Darby* case at p. 120.

The Court stated:

> "In passing on the validity of legislation of the class last mentioned [Congressional determination] the only function of courts is to determine whether the particular activity regulated or prohibited is within the reach of the federal power."

It is manifest that Congress itself has decided that the *misbranding* of drugs while they are being held for sale after shipment in interstate commerce sufficiently affects interstate commerce as to warrant and require federal regulation of the activity.

The government submits that Congress, in enacting Sec. 331(k), has kept within constitutional bounds. One of the principal purposes of the Federal Food, Drug, and Cosmetic Act is to prevent the use of the facilities of interstate commerce in conveying to and placing before the consumer misbranded articles of food and medicine. *McDermott v. Wisconsin,* 228 U.S. 115, at p. 131 (1913); *United States v. Two Bags * * * Poppy Seeds,* 147 Fed. (2d) 123, 127 (C.C.A. 6, 1945). This purpose could not effectively be accomplished if Sec. 331(k) had been omitted. The absence of this section would have made it relatively simple to render nugatory the misbranding provisions of the Act by simply shipping in interstate commerce properly labeled articles and misbranding them after the transportation had ended. Anticipating resort to such stratagem Congress sought to prevent it by enactment of Section 331(k) which would preserve the integrity of the labeling of an article that had been shipped in interstate commerce until it reached the ultimate consumer. It would be a futile gesture to require that drugs be properly labeled during their interstate journey and not be able to maintain the integrity of the labeling until the drugs reach the hands of the public. The facilities of interstate commerce are equally misused, and the same harm is spread to the people, whether the misbranding takes place before interstate commerce begins or after it ends.

> "Any rule * * * which is intended to prevent the flow of commerce from working harm to the

people of the nation, is within the competence of Congress."

Mulford v. Smith, 307 U.S. 38.

That a liberal and expansive interpretation should be extended to all sections of the Federal Food, Drug, and Cosmetic Act was urged by the Supreme Court in *United States v. Dotterweich,* 320 U.S. 277, which involved the criminal prosecution under said Act of a corporate officer for the acts of the corporation. It was there stated (p. 280):

> "The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words."

It was determined in *McDermott v. Wisconsin,* 228 U.S. 115, that Federal authority extended far enough to control the label of goods being offered for sale by a retailer to consumers after shipment in interstate commerce. In that case a Wisconsin statute required that certain types of syrup bear labels prescribed in the statute, and none other. McDermott, a retail merchant in that State received in interstate com-

merce a box containing 12 cans of syrup. These cans were placed on the shelves of his establishment, for retail sale. The labeling of the syrup when shipped in interstate commerce complied with the Federal Food and Drugs Act of 1906 but did not comply with the Wisconsin law. In order to meet the requirements of the State law it would have been necessary to remove the labels and substitute new ones. In holding that Wisconsin could not require the removal of such labels, the Court, in speaking of the State statute, said:

> "Conceding to the State the authority to make regulations consistent with the Federal law for the further protection of its citizens against impure and misbranded food and drugs, we think * * * to permit such regulation as is embodied in this statute is to permit a State to discredit and burden legitimate regulations of interstate commerce, to destroy rights arising out of the Federal statute which has been enacted under the constitutional power of Congress over the subject."

By Sec. 331(k) Congress has sought to protect and foster interstate commerce and prevent the impairment of other provisions of the Federal Food, Drug, and Cosmetic Act. This it may lawfully do. "It is the law that when Congress properly enters the field of its authorized activity it may not only adopt means necessary but, in a like manner, means convenient to the exercise of its power." *Board of Trade v. Milligan,* 16 Fed. Supp. 859, 861. Aff'd 90 Fed. (2d) 855; Cert. denied 302 U.S. 710 (1937).

In the *McDermott* case the Court held that the article had been shipped in interstate commerce and was therefore subject to federal authority to the extent of prohibiting a state from interfering with its label even after it had reached the shelves of a local retailer, that such interference by the State impinged against one of the lawful means Congress had chosen for the protection of the consumer. Since federal authority can require preservation of labels on articles that have been shipped in interstate commerce notwithstanding attempted state regulation, even where the article has become commingled with the property of the State and rests on the shelves of a local retailer, it follows that federal authority extends to the prosecution and punishment of acts that result in the articles being misbranded under like conditions. This, Congress did by the enactment of Sec. 331(k).

An important Supreme Court pronouncement with respect to the Food and Drugs Act of 1906 appears in the dissenting opinion of Justice Holmes in *Hammer v. Dagenhart,* 247 U.S. 251 (1919). The majority opinion was recently expressly overruled by a unanimous Court in *United States v. Darby,* 312 U.S. 100, where on page 115, the Court referred to "the powerful and now classic dissent of Mr. Justice Holmes." In his dissent in the *Dagenhart* case, Justice Holmes stated on page 279:

> "The Pure Food and Drug Act which was sustained in Hipolite Egg Co. v. United States, 220 U.S. 45, with the intimation that 'no trade can be carried on between the States to which

> it (power of Congress to regulate commerce) does not extend', 57, applies not merely to articles that the changing opinions of the time condemn as intrinsically harmful but to others innocent in themselves, simply on the ground that the the order for them was induced by a preliminary fraud. *Weeks v. United States,* 245 U.S. 618. It does not matter whether the supposed evil precedes or follows the transportation. It is enough that in the opinion of Congress the transportation encourages the evil."

Here Justice Holmes gave recognition to the proposition that in the Food and Drugs Act of 1906 Congress did not confine its regulation of interstate commerce in such merchandise to the period of transportation alone, but properly struck at evils intimately associated with such commerce, though they might arise prior or subsequent to the transportation.

Recently, the United States District Court for the Middle District of Georgia had before it substantially the same question as is raised in the instant case. The defendant there was also charged with violations of Section 331(k), Title 21, U.S.C., and the circumstances under which the violations were alleged to have taken place were similar to those in the present case. The defendant filed a motion to dismiss the information in which he attacked the constitutionality of Section 331(k) and urged that the provisions of the section were not applicable to the conduct charged as violations. The Court in denying the motion filed an opinion which contains a comprehensive analysis

of these two important questions. *United States v. Sullivan,* 67 F. Supp. 192.[1]

By the statute here in question Congress has in effect declared that if the facilities of interstate commerce are used for the shipment of goods, no person may thereafter, while the goods are being held for sale, do any act with respect to the goods which misbrands them. The mischief, which the statute seeks to prevent, has a direct effect on interstate commerce. To hold that Congress may not prohibit such acts would permit the facilities of interstate commerce to be used to the detriment of the public, and render nugatory in a wide field, its power to regulate commerce among the several states.

IV. CASES RELIED ON BY APPELLANT ARE NOT IN POINT.

The appellant relies heavily on *Schechter Poultry Corp. v. United States,* 295 U.S. 495 (appellant's brief, p. 19) to sustain his position that the acts which resulted in the misbranding of the articles of drug here involved were so remote from interstate commerce as to be beyond the control of Congress. The Government contends that the two situations are quite distinguishable. In the *Schechter* case the Court held that the constitutional grant of power to Congress to regulate commerce among the several States is not authority for the regulation of wages and hours of

---

[1]This case is now pending on appeal before the Circuit Court of Appeals for the Fifth Circuit.

employment in the strictly intrastate transactions of a local live poultry slaughter house market which does no interstate business; that even though the live poultry was transported in interstate commerce, it was in intrastate commerce when it came into possession of the Schechter company, and the wages and hours of the employees of such company so remotely affected interstate commerce as to be outside the sphere of Congressional authority. The Court said:

> "The question of chief importance relates to the provisions of the Code as to the hours and wages of those employed in defendant's slaughter house markets. It is plain that these requirements are imposed in order to govern the details of defendant's management of their business."

The purpose of the Federal Food, Drug and Cosmetic Act is very different. Congress enacted the law with the intent of denying the channels of interstate commerce to food, drugs, devices, and cosmetics which were adulterated or misbranded in a manner to constitute a threat of injury to the consuming public. The protection of the people of the Nation was uppermost in the minds of Congress in adopting this law. As stated in *United States v. Two Bags * * * Poppy Seeds,* 147 F. (2d) 123, 127 (C.C.A. 6):

> "From its inception, to its last amendment, The Pure Food and Drug Act was intended to protect the consuming public."

See also, *United States v. Antikamnia Co.,* 231 U.S. 654, 665.

And if, in order to achieve this legitimate end, Congress deemed it necessary to control certain intrastate activities which, if wrongfully used, could have the effect of nullifying the purpose and the intention of Congress in wielding its power over interstate commerce to prevent the transportation and placing before the public of misbranded and adulterated articles, it cannot be said that such activities so remotely affect interstate commerce as to be beyond Federal control. As was said in *United States v. Wrightwood Dairy Co.*, 315 U.S. 110, 119:

> "The commerce power is not confined in its exercise to the regulation of commerce among the states. It extends to those activities intrastate which so affect interstate commerce, or the exertion of the power of Congress over it, as to make regulations of them appropriate means to the attainment of a legitimate end, the effective execution of the granted power to regulate interstate commerce."

In the *Schechter* case the Supreme Court found that the provisions of the Code were *chiefly* directed at the control of the details of the defendants' management of their intrastate business. In effect the Court determined that this detailed management was so remote in its effect on interstate commerce as to be beyond the scope of the commerce power of Congress. In the present case, the acts of the appellant had such a *direct effect* on the power of Congress to control commerce among the States as to completely nullify the use of that power in preventing the misbranding of

certain articles of drug which had been transported from one State to another.

The appellant also relies heavily on *Walling v. Jacksonville Paper Co.,* 317 U.S. 564. (Appellant's brief, p. 10.) This case involved the Fair Labor Standards Act and is clearly distinguishable from cases under the Federal Food, Drug, and Cosmetic Act, Section 331(k), Title 21 U.S.C. The Fair Labor Standards Act was specifically limited in scope to articles "in commerce". On this point the Court said (p. 570):

> "In this connection we cannot be unmindful that Congress in enacting this statute plainly indicated its purpose to leave local business to the protection of the states * * * Moreover, as we stated in *Kirschbaum Co. v. Walling,* [316 U.S. 517], Congress did not exercise in this Act the full scope of the commerce power."

As previously shown in this brief, Congress in enacting the Federal Food, Drug, and Cosmetic Act intended to extend federal control to the farthest reaches commensurate with the power granted by the Constitution in the "commerce clause." The clear wording of section 331(k) discloses that Congress intended to control intrastate activities to the extent of preventing such activities from defeating the avowed purpose of the federal law.

The distinction between *United States v. Phelps Dodge Mercantile Co.,* 157 F. (2d) 453 (C.C.A. 9, 1947) (appellant's brief, p. 18) and the pres-

ent case is so fundamental as to need little discussion. The issues are entirely different. In the *Phelps Dodge* case it was contended that certain articles of food were adulterated while in the original unbroken package. The Court held that in order to seize and condemn an article under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(a)) it must be alleged and established that the article misbranded or adulterated when introduced into or while in interstate commerce, that alleging and proving an article was adulterated while in the original unbroken package after shipment in interstate commerce did not constitute an allegation that it was adulterated when introduced into or while in interstate commerce, and therefore that the libel did not state facts sufficient to warrant condemnation of the food. In the case under consideration, it is charged that the articles of drug were misbranded *after* shipment in interstate commerce and while being held for sale. It was stipulated by both parties that the drugs had been transported in interstate commerce and that they were subsequently misbranded while being held for sale. This constitutes the offense forbidden under Sec. 331(k) Title 21, U.S.C.

The appellant relies on *Weigle v. Curtice Brothers Co.,* 248 U.S. 285, for the purpose of construing and interpreting section 331(k), Title 21, U.S.C. The Court in that case was not confronted with the misbranding of articles held for sale after shipment in interstate commerce since the Federal Food and Drugs

Act of 1906, which was in effect in 1919 when the opinion was rendered, contained no such provision as Section 331(k). The Court considered only the validity of a Wisconsin State statute which was applicable in a field which the Federal Food and Drugs Act of 1906 did not touch, that is, the retail sales of articles of food after interstate shipment had ceased and the articles had been removed from the original packages. The Court did not consider whether these retail sales were intrastate activities which directly affected interstate commerce. The Act of 1906 clearly did not apply to such activities and the question was not raised. More recently, as previously shown in this brief, the Supreme Court, on numerous occasions, has held that the power of Congress over commerce among the states extends to intrastate activities which have a *direct effect* on interstate commerce. The "recognized line of distinction between domestic and interstate commerce" has not greatly changed since the *Weigle* decision, but the power granted Congress under Article 1, Section 8, paragraph 3 of the Constitution has been held not to be limited by "interstate commerce" but to extend to all activities directly affecting interstate commerce.

CONCLUSION.

In view of the foregoing it is respectfully submitted that the judgment of the District Court should be sustained.

Dated, San Francisco, California,
April 23, 1947.

FRANK J. HENNESSY,
United States Attorney,
EDGAR R. BONSALL,
Assistant United States Attorney,
Attorneys for Appellee.

LEONARD D. HARDY,
Attorney, Federal Security Agency,
Of Counsel.